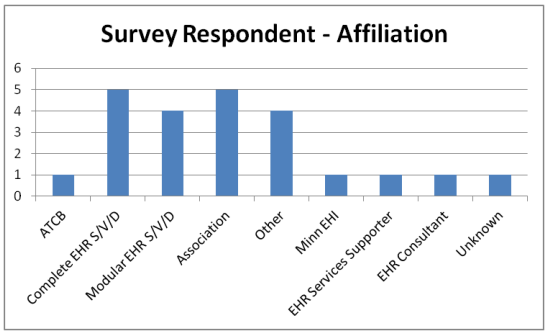

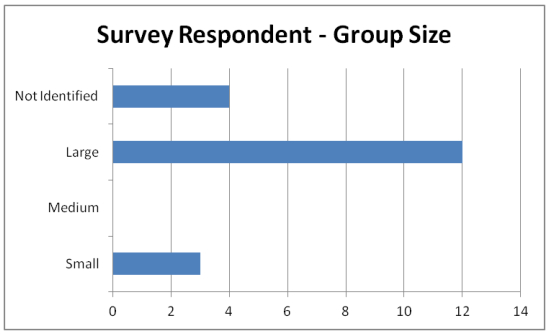

CERTIFICATION CRITERIA

GLOBAL ISSUES

most are known

- The word "transmit" has different meanings in different places
- Specificity of criteria - Do not address specialists and ancillary support activities
- Criteria are not clear enough - More detail should be added to the description of the criteria
- Vendors have too much flexibility to interpret the rules during their software design. Example given was NextGen's decision on how to define "unique patient." This misunderstanding was addressed by ONC/CMS.

CRITERIA STRUCTURE

comments on the balance of process-oriented vs. outcome-oriented

- Criteria are very heavy towards outcomes. More will need to be done on interdisciplinary criteria (consultant)
- Criteria are process-oriented.
    - EPs/EHs should be measured on outcome-oriented criteria. HITECH auditing process would be the appropriate place to measure outcome-oriented criteria. Clinical workflow should not be "prescriptively" specified in the certification criteria. Examples are OK, but EHRs should not be required to follow them exactly. (V/complete)
    - Results and outcomes should more closely align with EPs/EHs MU objectives and use of certified EHRs. An example of an overly process-oriented demonstration is the criteria associated with the smoking status (§ 170.302(g)). Over nine tests were required for each code, when a lesser number would have proved the function. Another example is the meaningful use objective to record and chart vital signs, calculated body mass index and plot and display growth (§ 170.302(f)). The testing process did not reflect the workflow that would be used by the provider to accomplish the objective and the purpose of the testing process was unclear. (V/complete)

CRITERIA – GENERAL COMMENTS OR RECOMMENDATIONS

- Provide computer-retrievable knowledge at the point of care. (person unaffiliated)

- Outside of the requirement for the CCR/CCD, very little in the MU criteria that addresses clinical workflow in a hospital setting.
- Interdisciplinary (and interdepartmental) application of checklists would greatly reduce care errors and costs. (consultant)
- Suggest more guidance and education to meaningful users to **make it clear where there are difference in the certification criteria and the MU incentive requirements**, such as the privacy and security certification criteria and the requirement for a security audit.
- An unintended side effect of the quality measures is that they require changes in software and workflow not specified by Meaningful Use. For example, in order to report on discharge medications for stroke and VTE patients, you must implement electronic script writing at discharge to record the discharge medications and associated RxNorm codes for inclusion/exclusion. (JH)

PUBLIC HEALTH SURVEILLANCE & REPORTING (LAB, SYNDROME AND IMMUNIZATION) — 170.302(x)

- Public health surveillance requirements were very vague
  - Public health surveillance. CCHIT noted removal of implementation guide, but testing and certification of products on the CHPL to the incorrect implementation guide.
- Conflict of Standards. Performing at least one test of immunization registry and reportable labs to public health using the standards. Since states and public health agencies vary quite a bit in the standards they require or support, it is very unclear what must be done for meaningful use when the states do not support the same standards as specified by ONC. Questions submitted to the CMS questions website on this issue have gone unanswered since August 2010 until now.
- Decompose: All of the public health reporting objectives could be decomposed to allow for public health reporting applications to be able to clearly standalone and be certified as EHR modules.
  - The criteria is defined to focus on the ability of the EHR to submit public health reporting data in a conformant manner to a defined specification, but the test procedure lays out a presumption that manual data entry in a source EHR need be the starting point for testing the criteria. The test procedure should allow for a starting point that the system is able to acquire the inbound data from a source system by showing how such inbound files are obtained.
- Lab Valid Values Structured lab objective. Despite the guidance that the lab result should be a numeric value or a positive or negative affirmation, there still was a lot of room for interpretation of what types of lab procedures and results should be considered for numerator credit. The challenge particularly came into play for result values that could be short textual strings.
- Recommend that criteria include requirements that laboratory result display and handling in an EHR is appropriate and flexible enough to account for the complexity of laboratory result display to support clinical interpretation and patient care. Only requires that CLIA requirements for laboratory reports are met.
  - Examples of testing that may require unique considerations in data display include: Microbiology, Blood bank/transfusion medicine, Molecular pathology and genetic

testing, etc. Examples of laboratory reports that may be prone to suboptimal handling in EHR systems include: reference ranges (normal ranges), reflex test orders and results, etc. (*See* CAP submission for entire lists and further detail)

- This is a good script. There are no specific examples to enter. The only issue is that there is no NIST validator for the HL7 2.5.1 generated. This is because of a mistake in the original Standards and Certification Final rule that specified an implementation guide for Disease Reporting, not Syndromic Surveillance. A revision to the rule removed the original implementation guide but did not specify a new one; Hence there is no implementation guide to certify against. This is a regulatory problem that should be fixed soon. (JH)

INCORPORATE LAB RESULTS	170.302(h)

- The lab system and their EHR may share a common database. If not, HL7 2.5.1 should be used to transmit data between a external lab systems and the EHR. This script does not support integrated databases nor HL7 2.5.1 standards; Instead it requires that any structured format be sent from a lab system to the EHR. I'm not sure what policy or technology benefit such a demonstration creates.(JH)

ERX	170.302(x)

- eRx (are OTCs excluded?)
- eRx was initially a disaster since new fields were added and no one coordinated with Surescripts

SMOKING STATUS	170.302(g)

- The only challenge is that you must adhere to the CDC's smoking codes precisely (1=Current every day smoker, 2=Current some day smoker, etc.) despite the fact that the regulation lists only text values and doesn't require the CDC numeric recodes. (JH)

EXCHANGE OF HEALTH INFORMATION	170.302(x)

- Unclear what method of exchange is required for exchange of health information

CALCULATE AND SUBMIT CQMS AND AUTOMATED MEASURE CALCULATION	170.304(j), 170.306(i), 170.302(n)

- Suggest that vendors be allowed to test against a subset of measures for reporting. / CQMs for emergency departments.
    - These criteria require that a vendor report on all measures (CQMs and objectives), but some vendors test against only a subset of objectives, while others are specialty systems that may be able to report only on specific quality measures.
- The current test scripts explicitly state that accuracy of measurement will NOT be tested, and the measures include many data elements that are not routinely collected in the EHR, as well as sophisticated concepts that may require clinical judgment to address (such as the time a physician decided to admit a patient seen in the emergency department). Fix emergency department. (AHA and V/complete)
- CQMs (§ 170.304(j) and § 170.306(i)) and auto measure calculation (§ 170.302(n))

- Wide interpretation of what should be in the numerator and denominator between ATCBs and vendors (provide more clarification on this topic) (*see* CCHIT specific comments in their submission).
- Test scripts did not test for exceptions even though providers have that option during their attestation process

- The script is fine, but the HITSP document which underlies it contains a few mistakes. The exclusion and inclusion criteria for VTE-6 are incorrect. (JH)
  - The HITSP quality measures specification was created before the Standards Final Rule was developed, so although both ICD-9-CM and SNOMED-CT are allowed by the Final Rule, the HITSP specification defines the quality measures using only SNOMED-CT terminology. This means that every vendor and hospital has to create their own mappings to ICD-9-CM for all the quality computations.

EMERGENCY ACCESS	170.302(p)

- Match to Final Rule and test both "Break the Glass" for a patient medical emergency and also for situations like natural disaster emergencies.

DRUG-DRUG, DRUG-ALLERGY INTERACTION CHECKS	170.302(a)

- The appropriateness of disabling drug-allergy interactions should be reviewed and removed from the scope of this criterion for patient safety reasons.

MEDICATION RECONCILIATION	170.302(j)

- The current criterion and test method do not test true medication reconciliation.

VITAL SIGNS, BMI & GROWTH CHARTS	170.302(f)(1) (2)and (3)

- Does this apply as is at all care levels and delivery methods? For example, vital signs – growth charts. Client is considering adding growth charts to its product due to competitive reasons because getting certified on the 'vital signs' certification criterion is important, yet their customers (specialty/ancillary providers) will have no real need for that capability.

RECORD DEMOGRAPHICS	170.304(c)

- Why is date of death required?
  - If I can register a patient into an ancillary product such as an ICU unit, Lab, anesthesia, etc, why would you need death of death? As part of a full EHR for the front end intake process I can understand the value of that info, but why is it needed for Modular certification? (consultant)

EXCHANGE CLINICAL INFORMATION	170.304(9)

- Means of transport of the clinical information was not specified (no standards)
  - The impression was left with many organizations that any electronic transport would be acceptable. However, CMS recently surprised many with the ruling that use of portable electronic media is not acceptable. This should have been much clearer in the regulations

and the tests, if only certain ways of exchanging (e.g., via network but not via media) were accepted. (V/complete)

CPOE	170.304(a)/ 170.306(a)

- Certification criteria require that a vendor show CPOE for medication, laboratory, and radiology/imaging orders. Why do the criteria require additional order types (confusion)?
- Additionally, at first, there was just too much vagueness in who could place an order and have it counted, the types of orders that could be placed and what types of workflows for entering orders could be accommodated. If the intent was to promote physician adoption, it seems at odds with that intent to allow for all manners of order transcription to be considered (*See* Cerner's (John Travis) full submission for specific questions)
- CPOE will meet goals for laboratory test ordering only if; (1) capabilities that are necessary to meet requirements of all of the nuances of laboratory test ordering exist in the CPOE system/module; and (2) organizations and providers using CPOE configure the CPOE system in a way that ensures proper ordering of laboratory tests. (*See* CAP submission for further details)

	170.304(i)

- Recommend § 170.304(i) include diagnostic images in the types of information that a certified EHR is required to electronically receive, display and transmit. Also recommend adoption of DICOM.

SUMMARY OF CARE RECORD & PROVIDING ELECTRONIC COPY OF HEALTH INFORMATION	170.306 (d)(1) and (2)

- The certification requirements for *summary of care record* and *providing patients a copy of their health information* contained a smaller set of data elements than the requirements on providers for meeting meaningful use. This has generated considerable confusion. We recommend limiting the requirements on providers to the information that can be generated by certified EHRs. (AHA)
- *Electronic copy of the record* objective. Unclear how the record could be provided, the form it needed to be provided in, whether that needed to be singular or multiple electronic files/outputs and what content really needed to be included as well as the impacts of any conditions the patient might place on the request (*See* Cerner's (John Travis) full submission for questions related to patient requests).

CLINICAL SUMMARIES	170.304(h), 170.306 (f)

- Content of the clinical summaries CCD C32 conflict with CMS definition of their measures.
- Summaries of care criteria are not aligned with test procedure

ACCOUNTING OF DISCLOSURES (OPTIONAL)	170.302(w)

- We elected not to demonstrate this. I'm not sure why optional requirements are included in certification. (JH)

SECURITY & PRIVACY INCLUDING AUDITING, ENCRYPTION AND INTEGRITY	170.302(o) – (v)

- Combine authentication & access controls
    - There are four test steps that are entirely repeated between access control and authentication. Another example is for testing encryption of data in transit and general encryption. We are aware that ATCBs have allowed vendors to test both of those procedures with the same example of encryption. Either combine the two test procedures or require different encryption capabilities to be tested between them.
    - Recommend that the testing processes for security scripts that cover the different types of access and controls (§ 170.302 (o), (p), (q) and (t)) and the security scripts that cover integrity and encryption (§ 170.302(s), (u), and (v)) be combined.
- Decompose: Audit test procedure should be decomposed into two procedures to allow for security audit log products to be able to be tested independently.
- Application of privacy and security criteria, including exemptions, to EHR modules and for site certification needs to be clear and less burdensome.
- Little correlation between steps the provider must take to conduct or review their security risk and requirements of the vendor in testing the security and privacy scripts, (§§170.302(o)-(t)). In particular, the integrity and encryption scripts were unclear as to what was expected during testing and what specific output was deemed to be acceptable. Further, the testing and output required from the EHR did not align with provider workflow or the intended use for the EHR relative to the security risk.
- Attestation should be permitted when demonstrating encryption, when standard built-in features (e.g., browser, OS) are used. This is equivalent to distrusting your browser's HTTPS encryption, and the test procedure essentially requires inserting a test tool (not part of the product) to demonstrate something that is normally "invisible."
- The final three security demonstrations (Integrity, Gen Encryption, and Encryption when exchanging EHI) are all very odd. All three criteria should be revised to use attestation, not demonstration. 302(s)(u)(v) (JH)
    - HIEs use data integrity protections and encryption to ensure data travels from point A to point B without modification. The script requires demonstration of a test harness, not a live system, because encryption and hashing are invisible, just as HTTPS in your browser is invisible.

Specialty Areas

- Decompose all criteria that can impact specialty areas
- Criteria do not adequately address interoperability and information exchange capabilities for image-based specialties such as ophthalmology, radiology, and cardiology. (AAO)
- Few vendors comply with data representation and exchange standards. Creates a significant obstacle to widespread adoption by the specialty, including difficulties involving manual data re-entry into patient records, image data residing in multiple locations, the need to scan results into EHR systems, and the need to develop proprietary device interfaces. Concerned that this increases the risk of errors when such electronic data are entered incorrectly or not available at the point of care.

- EHRs as defined by ONC rules are not used in pathology. Pathologists and their laboratories have long relied on laboratory information systems (LISs).
- Specificity of criteria: Does not address specialists and ancillary support activities
    - Dentists are EPs, yet there are no oral health measures in meaningful use or standards for certified electronic dental records (EDRs). EHRs were not created for a dental practice.
    - ONC should develop a certification standard, in cooperation with the ADA, specifically for EDRs that will make the certification program more accessible to oral health professionals.

TEST PROCEDURES

PROCESS *release process should be formalized & structure around clinical workflow*

- There should be a more formal process for release of test procedures, collection of feedback, and publication of final test procedures, with scheduled dates associated with each step. Clinical and vendor review will also help catch basic mistakes in the procedures related to content, such as discontinued medications that were included in the scripts. As to process, it could be handled via an open web-based process and/or e-mail box to submit questions, suggestions for improvements, and clarifications. (V/complete)
    - Version test scripts. Since test procedures can be continuously changed, it introduces unnecessary uncertainty to developers. Recommend that test procedures be versioned and that those who passed certification according to the then-current version not be required to retest. (modular and complete vendors - multiple)
    - Recommend that test scripts and changes to test scripts be announced (at least 60 days) in advance. (V/complete)
- Formatting the NIST test procedures in the form of a script would be useful. (V/complete)
- Consider organizing the test procedures in the order they would be performed during a patient's typical hospital or clinic stay. (V/complete)
    - Test procedures that align to a clinical workflow could be combined into a story of sorts that provides for a linear flow to allow for multiple test procedures to be tested in one overall flow.
    - Adding clinical context to the actual test procedures may go a long way towards facilitating this goal. Our ATCB produced test scripts that incorporated patients and office visits into the scripts, which helped give us a better idea of the clinical workflows we would demonstrate during the test and clarified what we needed to do for certification preparation. (V/complete)
        - For EPs, CPOE, CDS, drug based alerting and eRx could be tested together.
        - For hospitals, CPOE, CDS, drug-formulary checking and drug based alerting could be tested as a continuous flow.
        - Other combinations also seem possible centered on discharge or departure from a physician office including medication reconciliation, discharge instructions or patient education and providing an electronic copy of the record. (V/complete)
- The NIST scripts require demonstration of functions that may not be part of standard clinical workflow. (JH)
    - During certification, I wanted to demonstrate live transmission of transactions to the Massachusetts Department of Public Health and Boston Public Health Commission. Neither of these real public health transmissions were acceptable because the NIST security script requires the demonstration of encryption and hashing in real time. This is equivalent to not trusting the HTTPS in your browser and requiring browsers to display the actual encryption taking place for every web page retrieved. The NIST scripts should be revised to enable attestation of the use of FIPS compliant encryption for Stage 1. Hopefully for Stage 2, there

will be enough specificity in transport standards so that the test can be accomplished by submitting data to a NIST specified website that illustrates adherence to the transport standard (NHIN Direct, NHIN Connect etc.)

- Several of the NIST scripts require data entry that seems clinically unusual. (JH)
  - For example, you must place a CPOE order for Darvocet for pain control, even though Darvocet has been removed from the market by the FDA. Many of the medications included in the scripts are unusual brand name medications that may not be on a hospital's formulary.
  - One data set in the Reportable Lab script requires that you send a public health entity information about an infection the patient does NOT have (Stool Culture with a negative result for Shigella).
- The NIST scripts require that you demonstrate data entry of information that is not normally entered by clinicians in a hospital. The typical workflow for labs is that they are ordered from an external provider (Quest, Lab Corp) or processed by internal lab systems then inserted into the EHR via an HL7 transaction. The NIST scripts should be revised to clarify that labs should only be shown, not entered. Diagnosis and Procedure codes are typically created by Health Information Management after discharge and are sent from a Utilization Review system to the EHR via an HL7 transaction. The NIST scripts should be revised to clarify that data elements not entered by the clinician should only be shown, not entered. (JH)
- Recommend that the ATCBs develop and deploy additional validation tools to eliminate the guesswork for some of the record layouts and data elements.
  - NIST tools that are used prior to and during testing to validate many of the scripts output are incomplete. Therefore, the ATCB proctors were required to conduct a visual inspection of some of the records and XML before certifying the vendor's EHR. (V/complete)

Test Procedure - General

- The word "transmit" has different meanings in different places
- State expected results. If it is up to the vendor for display, then say so. State why things are needed a certain way. Interpretation was difficult. (V/modular)
- Examples of valid testing approaches within the context of the test procedures would serve to help vendors prepare. (V/complete)
- Don't use obsolete drugs
- ? Patient list by conditions in the original test script from NIST. (V/complete)

Drug Drug / Drug Allergy / Allergy Interactions — 302(a)

- The only challenge is that you must demonstrate how decision support can be disabled for drug/drug and drug/allergy interactions. I can understand disabling selected drug/drug interactions to reduce alert fatigue, but I cannot think of a clinical reason to disable drug/allergy interactions. (JH)

Timely Access — 304(g)

- Test procedures for timely access (§ 170.304(g)) did not correspond to a typical eligible provider workflow or the process required to connect a patient to their practice to provide online access to their clinical data.

- Although the provider's measures require timely access within four business days to 10% of their unique patients, the testing scripts were not clear on the support that would be initiated by the provider. (V/complete)

SMOKING STATUS	170.302(g)

- An example of an overly process-oriented demonstration
  - Over nine tests were required for each code, when a lesser number would have proved the function.

PLOT AND DISPLAY GROWTH CHARTS	170.302(f)

- Entering the data required for the demonstration is a lengthy process. Best to revise the script to require only display of data, then graphing.

GENERATE PATIENT LISTS	170.302(i)

- I believe that the spirit of the Policy and Standards Committee was to be able to demonstrate a single analytic query on EHR data. The script goes much further than that, requiring filtering and sorting on problems, medications, and lab values. I believe the script should be revised to allow a simpler demonstration of business intelligence using EHR data. (JH)

	170.302(k)

  - This is a great script! The clinical examples are accurate and are typical of the data elements captured in the real world. The NIST validator tests real HL7 2.5.1 transactions and the implementation guide is very clear. (JH)

CPOE	170.304(a)

- Separate the testing of a radiology and laboratory order from a medication order type. In many EHRs, those applications are sold and installed separately. (V/complete)

ERX, ORDERING AND DRUG-FORMULARY CHECKS	170.304(a), 170.304(b), 170.302(b)

- Recommend combining medication ordering, electronic prescription and drug-formulary checking scripts (§§ 170.304(a), 170.304(b) and 170.302(b)). (V/complete)

EXCHANGE	170.306(d), 170.306(f), 170.304(i), 170.304(f)

- There is redundancy with the exchange scripts (§ 170.306(d) with § 170.306(f) and § 170.304(i) and § 170.304(f)). Recommend they be combined or tested together. (V/complete)

CLINICAL SUMMARIES	170.304(h)

- Test method for § 170.304(h) requires that vendors provide clinical summaries electronically. This electronic requirement seems to go above and beyond the criterion itself. (V/complete)

  - The criterion requires that clinical summaries are provided to patients via the EHR, but only states "*if the clinical summary is provided electronically…*"
- Data necessary for generating the CCD - it is difficult to backdate data.

EXCHANGE CLINICAL INFORMATION AND PATIENT SUMMARY RECORD	170.306(f)

- The appropriate style sheets should be included in the script with instructions on how to use them.
  - 306(f) is a good script but it duplicates 170.306 (d)(1). The first part of the script requires incorporation of a CCR and a CCD into the EHR in human readable form. To do this, the appropriate Extensible Style Sheet (XSL) reference needs to be inserted into the files and the CCD.xsl and CCR.xsl need to be downloaded and placed in the same directory. How is a hospital IT department supposed to figure this out? (JH)
  - The second part of the script is to generate a CCD based on complex data sets which include multiple elements that clinicians do not normally enter (hospital generated diagnosis and procedure codes). The script should be revised to require only display of data, rather than entry, followed by CCD or CCR generation. The CCD validator created by NIST uses the HITSP C83 specification which was published before the Standards Final Rule was developed. HITSP C83 required problem lists to be coded in SNOMED-CT, but the final rule allows ICD-9-CM and SNOMED-CT. You'll need to read Keith Boone's blog for step by step instructions to create a CCD with ICD-9-CM codes that passes validation.

ELECTRONIC COPY OF HEALTH INFORMATION	170.306(d)

- (d)(1) This script should be eliminated because it is a duplication of 170.306(f) with slightly different data sets for generation of the CCD and CCR. (JH)
- (d)(2) Very well written, no issues. There is a great degree of flexibility to create and save discharge communications intended for providers. There is no test data and no standards conformance testing. (JH)

REPORTABLE LAB RESULTS	170.306(g)

- This is an odd script. The examples are all "send out" labs from outside laboratories but the script requires demonstration of the data being entered. How can you enter data provided by an outside lab? This script should be revised to require only display of data received from an outside lab that was incorporated into an EHR. (JH)
  - The first sample data set for this script is reasonable - a lead level. The other samples are more complex than is necessary for demonstration of public health reporting (three instances of the reason for reporting, a corrected result, and reporting of a disease the patient does NOT have - negative result for Shigella). This is good example of a script that needed to be pilot tested before requiring its use.

CALCULATE AND SUBMIT CQMS AND AUTOMATED MEASURE CALCULATION	170.304(j), 170.306(i), 170.302(n)

- The current test scripts explicitly state that accuracy of measurement will NOT be tested, and the measures include many data elements that are not routinely collected in the EHR, as well as sophisticated concepts that may require clinical judgment to address (such as the time a physician decided to admit a patient seen in the emergency department). Fix emergency department. (AHA and V/complete)

- CQMs (§ 170.304(j) and § 170.306(i)) and auto measure calculation (§ 170.302(n))
    - Wide interpretation of what should be in the numerator and denominator between ATCBs and vendors (provide more clarification on this topic) (*see* CCHIT specific comments in their submission).
    - Test scripts did not test for exceptions even though providers have that option during their attestation process

SECURITY & PRIVACY	170.302(o) – (v)

- More specifics and directions for integrity and encryption (apply to CCR & CCD?). (consultant)
- Recommend that the testing processes for security scripts that cover the different types of access and controls (§ 170.302 (o), (p), (q) and (t)) and the security scripts that cover integrity and encryption (§ 170.302(s), (u), and (v)) be combined.
- Little correlation between steps the provider must take to conduct or review their security risk and requirements of the vendor in testing the security and privacy scripts, (§§170.302(o)-(t)). In particular, the integrity and encryption scripts were unclear as to what was expected during testing and what specific output was deemed to be acceptable. Further, the testing and output required from the EHR did not align with provider workflow or the intended use for the EHR relative to the security risk.
- 302(p) I'm truly confused by the intent of this test script. I do not know of any Policy or Standards Committee intent to demonstrate the ability for users (not administrators) to override security controls and obtain access to clinical data. We demonstrated it successfully, but I am unaware of this being a mainstream or desirable function in an EHR.
- 302(r) The audit log script requires the ability to filter and sort the log by numerous criteria. I am unaware of any Policy or Standards Committee intent to demonstrate advanced analytics on audit logs. (JH)

CPOE	170.304(a)/ 170.306(a)

- The challenge is that the required medications are very odd. Cefzil (cefprozil) suspension is likely not on most hospital formularies. Darvocet has been removed from the marketplace by the FDA. This script needs to be revised to reflect mainstream medications used in live healthcare settings.

ACCOUNTING OF DISCLOSURES (OPTIONAL)	170.302(w)

- Description/test was very brief and does not provide enough information for the vendor to assess its capability. Lack of clarity may have contributed to why only a few EHRs tested against this script.

TEMPORARY CERTIFICATION PROGRAM

PROGRAM - GENERAL

- Lack of clear guidance to ATCBs has led to inconsistency. (V/modular, AHA and CCHIT)
- Suggest (better structure) through the creation of a single resource (comprised of coordinated representatives from both ONC and CMS, for example) and a single location (one website) for guidance and for submitting questions.
- Additionally, we suggest including a comprehensive revision history for each FAQ. Today, it is easy to find FAQs that have been updated but often the change is only one word or a typo correction.
    - To determine whether a substantial change was made, we must record the text of each FAQ in order to identify changes in subsequent updates. (V/complete and AHA)
- "…some risk that purchasers who acquire systems under that Temporary status, will not get a fully-certified product, since a vendor can elect to discontinue prior to permanent certification." AAP
- Certify other HIT
    - including PHRs, networks for health exchange, etc.
    - ONC should work with AAP on end-products that pediatricians need.
- Recommend integration and interoperability testing of EHR Modules and components of Complete EHRs as part of the certification process.
- Possession
    - Financial burden on vendors to certify multiple combinations. (AHA)
    - Financial burden on providers. (Minn e-Health)

    - ONC should educate providers on a modular purchasing approach (and/or) not require them to purchase the entire Complete EHR. (V/modular & Minn e-Health)
        - Recommend ONC requiring vendors obtain modular certification of their products. (V/modular)
        - Possession of entire certified Complete EHR leads to redundant licensing for customers/providers. (V/complete and AHA)
        - Bias towards Complete EHR vendors or single-vendor solutions. (2 V/modular, consultant, and AHA)
        - "Best-in-breed" EHR Module developers have a hard time convincing EPs/EHs to buy duplicative products. (2 V/modular and consultant)
        - *Derivation.* Allow vendors to sell and providers to purchases "parts" of a certified Complete EHR. (V/complete and AHA)
- Pricing
    - Establish pricing mechanisms for certification. (Minn e-Health Initiative)
    - Why do ATCBs have different price points? (V/modular)

CERTIFICATION

- When is site certification required? (Minn e-Health)

- Determining whether the EHR technology installed in a particular hospital or physician office meets the certification criteria has been an unexpected challenge. (V/modular and AHA)
- Allow providers to modify or substitute technology components incorporated into a criterion as long as the original EHR was certified.
- Expected that hospitals (and EPs) must have CEHRT only for whichever modules they were going to use for MU. (V/complete and AHA)
- Confusion about providers implementing certified systems and running them in conjunction with non-certified systems. ONC FAQs have tried to address this but there are still many questions/issues.
    - For example, if I run a certified EHR Module and a non-certified Module and both pass data into (or take data from) an interface engine and the engine also sends data to a QM database, is the QM tool considered to meet MU? Does the interface engine need to be certified (at least for P&S)? (consultant)
- Inherited Certified Status (new releases)
    - The area of "new releases" needs to be addressed. There is little or no direction on this and issues such as updates / fixes /patches to systems need to be considered.
    - A better formulated description of when attestation would be enough for recertification and when retesting would be required. This should take into account the possibility of situations where there are minor product changes in some program areas (which could be attested to) even if there are more significant changes in other areas (which would require testing).
    - Saw situation where certification for a complete EHR was also given to EHR Modules for the same vendor. Seemed criteria from the complete EHR were 'inherited' into the Module. For example, a vendor with modular certification for an anesthesia system was approved for a CQM for emergency wait times. What do ER wait times have to do with an anesthesia system? (consultant)
- Certification overlaps logical product boundaries (3rd party software). A modular approach may not be efficient for hospital developers who need to certify previously installed EHR technology. Hospital developers use various "best-in-breed" products and may need to certify previously installed EHR technology. In some cases, they may have two or more products that "straddle" one ONC criterion. More guidance should be given to ATCBs related to certification in this area. (large vendors and CCHIT)

CERTIFIED HIT PRODUCTS LIST (CHPL)

- CHPL reporting rules
    - Multiple listings of vendors various certified EHR Modules as it pursues Complete EHR certification is confusing. Updating product certification line items with added functionality as they are achieved when pursuing Complete EHR certification would simplify the CHPL. Clarity is also required for modifying a certification once listed. (CCHIT)
    - Doesn't reflect industry bundling or branding terminology. Recommend clarification of the vendor applications within the EHR product that are required for each criterion, including a notation of the required sub-applications or products in the Module or Complete EHR. This will assist providers in selection. (V/complete)
- Make publically available all CMS EHR certification IDs created on the CHPL. (AHA)

UNEXPECTED GAINS

- Assisting providers and building relationships (V/modular)

- Learned that the value of the complete EHR certification was not as expected. Modular certification would have been better for the majority of clients. (V/complete)

WORKED WELL

- Distribution of information, access via web, blogs, FAQs. (consultant)
- Guidance and processes provided by ATCBs (and ONC). (V/ Modular, C)
- Choice of testing and certification bodies. (V/complete)
- Remote testing capabilities. (V/complete)
- Consistency of standard NIST test procedures, although there were some variations (V/complete)
- Modular certification and the ability to pursue site certification. (AHA)